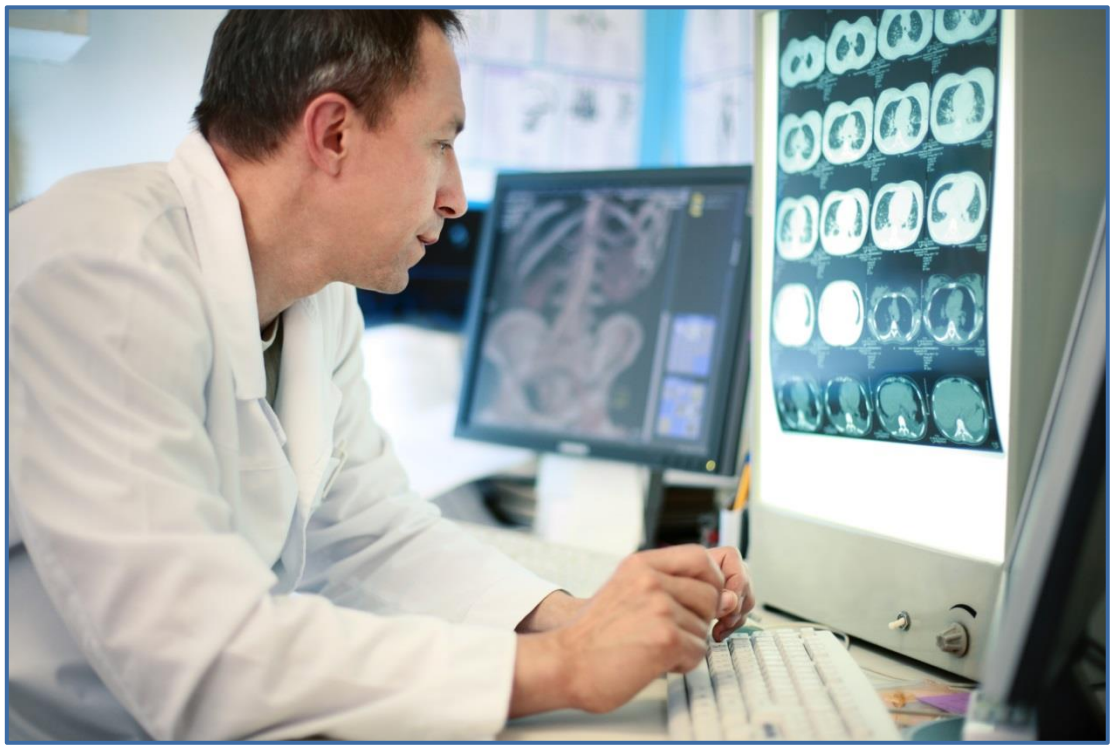
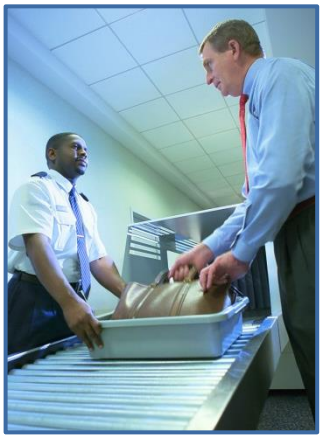
State of Delaware

Radiation Control Program

Annual Report 2014





DELAWARE HEALTH
AND SOCIAL SERVICES
Division of Public Health

The Office of Radiation Control Program

Introduction

Federal and state regulations require that radiation source facilities maintain a radiation protection program to assure that radiation devices are installed, operated, and maintained in a way that protects the public, workers, and patients from unnecessary radiation exposure. Health care credentialing organizations require that individuals who administer radiation to human patients meet certification requirements to ensure patient safety, limit radiation dose to levels as low as reasonably achievable (ALARA), and promote positive health outcomes. The regulatory mission space for radiation protection is broad and diverse. Key governmental organizations dedicated to monitoring radiation protection in Delaware are described below.

State of Delaware, Authority on Radiation Protection (the Authority)

The Delaware Authority on Radiation Protection, established in 1976, consists of members appointed by the Governor. This public board has statutory authority to effectively regulate sources of ionizing radiation to protect occupational and public health and safety. The Authority is tasked with establishing a regulatory system within the state that permits maximum utilization of ionizing radiation sources for peaceful purposes, consistent with the public health and safety. The enabling legislation for the Authority is Title 16, Delaware Code, Chapter 74, Radiation Control. The Act identifies the Office of Radiation Control as the Administrative Agent for the Authority. Radiation control legislation was first enacted by the state in 1953, and was last amended in 2008. The Authority establishes regulations under the Radiation Control Act that reflect developments within the practice community and the emergence of a wide array of technologies utilizing ionizing radiation sources for peaceful purposes.

Office of Radiation Control, Division of Public Health (the Agency)

The Office of Radiation Control carries out the state regulations established by the Authority. The Office of Radiation Control annually inspects FDA-certified mammography facilities in Delaware, registers and periodically inspects radiation machine facilities for compliance, and registers radioactive material facilities. The Office of Radiation Control also registers radiation service providers (vendors), investigates reportable events or incidents involving radiation sources, and provides consultation and coordination with other parties who have an interest in radiation protection in Delaware. This program report provides an overview of major operational work flows managed by the Office of Radiation Control in calendar year 2014.

Office of Radiation Control Program, January 1 – December 31, 2014

Radiation Machine Facility Operations	
Facilities holding registration permits	649
Facility permits amended or renewed	685
New permits issued	21
Radiation machine facilities inspected	329
Inspection violations issued	78
Administrative penalties issued	0
X-ray Devices (tubes) inspected	938
Office home page: number of web hits	10,204

Radiation Technologist/Technician Certification	
Individuals holding certificates	2,652
New certificates issued	330
Existing certificates renewed	388
Certificates sanctioned (enforcement)	0

Radioactive Material Facility Registration	
Facilities holding registration permits	103
Facility permits renewed	5
New permits issued	3

Radiation Service Provider Registration	
Companies/persons holding permits	168
Provider permits renewed	35
New permits issued	9

Radiological Emergency Preparedness (REP) Operations	
Public health staff assigned	6
Number of REP events: planning, training, drills, graded exercises, and public outreach events	12
DPH staff hours expended on REP events: planning, training, drills, graded exercises, and public outreach events	525

Authority on Radiation Protection, Administrative Agent Duties	
Quarterly public meetings	4
Press conferences	1
Committee meetings	5
Committee teleconferences	3
Public hearings	1

Source: Delaware Office of Radiation Control, March 2015

Delaware Radiation Control Regulations Executive Order 36 Review Status			
Amended Regulation Effective Date	**Proposed Rule Publication Target Date**	**Current Delaware Regulation DDRT**	**Title**
5/11/2014		4465 Part A[1]	General Provisions
5/11/2014		4465 Part B	Registration of Radiation Source Facilities & Services
6/11/2013		4465 Part C	Licensing of Radioactive Material
	5/1/2015	**4465 Part D[2]**	**Standards for Protection Against Radiation**
		4465 Part E[3]	Radiation Safety Requirements for Industrial Radiographic Operations
6/11/2013		4465 Part F	Use of Diagnostic Imaging in the Healing Arts
6/11/2013		4465 Part G	Use of Radionuclides in the Healing Arts
		4465 Part H	Radiation Safety Requirements for Analytical X-Ray Equipment
		4465 Part I	Radiation Safety Requirements for Particle Accelerators
	5/1/2015	**4465 Part J**	**Notices, Instructions and Reports to Workers; Inspections**
6/11/2013		4465 Part K	Compliance Procedures
		4465 Part T	Transportation
6/11/2013		4465 Part X	Therapeutic Radiation Machines
5/11/2014		4466	Certification of Radiation Technologists/Technicians

Source: Delaware Authority on Radiation Protection, March 2015

[1] As of May 2014, eight chapters of radiation control regulations (4465 Parts A, B, C, F, G, K, X and 4466) were published as final rule by the Register of Regulations.

[2] As of February 2015, two chapters of radiation control regulations (4465 Parts D & J) were approved by the Authority on Radiation Protection. The DPH Director submitted the chapters as a proposed rule for public comment, with target publication date of May 1, 2014.

[3] As of February 2015, four remaining chapters of radiation control regulations last amended in 2002 require review (4465 Parts E, H, I, & T). The timeframe for review of this set of regulations is under review by The Authority on Radiation Protection in 2015.

Federal Partners

U.S. Food & Drug Administration (FDA)

The Radiation Control for Health and Safety Act of 1968 authorized the U.S. Food and Drug Administration to set federal radiation standards for electronic radiation emitting devices, monitor compliance, and conduct research. The FDA's Bureau of Radiological Health actively administered the Act, and promptly called a meeting of the states to discuss implementation following passage of the Act, focusing on the growing public health problem of exposure to radiation. Sections 356 and 357 of the Act emphasized the importance of state involvement in its implementation, and identified measures and assistance needed to strengthen state radiation control programs. Implementation of the federal Act resulted in enactment of state radiation control statutes nationwide. Recognizing state resource challenges, the FDA provided funding and consultation to establish the non-profit, non-governmental organization called the Conference of Radiation Control Program Directors (CRCPD) in 1968, to develop peer-reviewed state model regulations and promote a more consistent national approach to operational safety and health protection in radiation machine facilities. CRCPD continues to operate with partial funding from the FDA and other federal partners, the Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), Federal Emergency Management Agency (FEMA), and Department of Energy (DOE), as well as professional societies, such as the American Association of Physicists in Medicine (AAPM), American College of Radiology (ACR), American Society of Radiation Oncology (ASTRO), and Health Physics Society (HPS).

The Mammography Quality Standards Act (MQSA) of 1992 authorized FDA to certify and inspect mammography facilities to establish and monitor minimum standards for radiation machine parameters, quality assurance, and professional training/experience for mammography device operators. Under the MQSA Act administered by the FDA Bureau of Radiological Health, the FDA contracts with state radiation control programs to provide annual, onsite inspections of accredited mammography facilities within their jurisdiction, and identify violations for follow-up and enforcement by the FDA.

U.S. Nuclear Regulatory Commission (NRC) and Federal Emergency Management Agency (FEMA)

The Atomic Energy Act of 1954 was amended in 1970 to organize governing authority for oversight of nuclear materials in the defense sector to the U.S. Department of Energy, and specifies governing authority for oversight of radioactive materials in the civilian sector to the U.S. Nuclear Regulatory Commission. The Atomic Energy Act was later amended by The Energy Policy Act of 2005 to expand federal authority for licensure and enforcement of civilian radiation sources, and to expand accountability and safeguarding of radiation sources for purposes of homeland security. Under the Energy Policy Act of 2005, additional requirements were implemented for radiation source tracking, vetting authorized users of safeguarded sources, and critical infrastructure protection in the nuclear sector. The Delaware Office of Radiation Control (ORC) is the lead state agency for civilian radioactive material source regulation, with licensing and enforcement of radioactive material facilities carried out by the NRC Region 1 office, in King of Prussia, PA.

U.S. Nuclear Regulatory Commission (NRC) and Federal Emergency Management Agency (FEMA) (cont.)

The NRC issues operating licenses to corporations that own or operate commercial nuclear reactors used to generate electrical power, issues operating licenses to research reactors used to generate radioactive materials for biomedical or pharmaceutical purposes, and provides on-site inspections and monitoring of such reactor facilities for public health and safety. The Federal Emergency Management Agency (FEMA) establishes standards for emergency preparedness and response capabilities that must be maintained by nuclear power utilities and off-site response organizations (state/local governments). FEMA periodically evaluates response and recovery capabilities utilizing full-scale, multi-agency exercises that simulate radiological emergencies resulting in releases of radioactivity to the environment. Exercise evaluation criteria include development of protective actions that prevent or limit radiation dose to the public. The Delaware Emergency Management Agency (DEMA) is the lead state agency for the Delaware Radiological Emergency Preparedness (REP) program and works closely with the FEMA Region 3 office in Philadelphia, PA.

Copies of this report are available by contacting the Office of Radiation Control at 302-744-4546, or by visiting http://www.dhss.delaware.gov/dhss/dph/hsp/orc.html